

REMARKS

I. Status of the Claims

Claims 1 and 6-30 were previously pending in this application, with claims 8, 10, 12-14, 19-22, and 24-28 withdrawn from consideration for the time being. The Examiner has indicated that the isolated cell deposited at DSM under the number DSM ACC2548 and the antibody produced by the cell as recited in claims 7 and 18, respectively, are free of art.

Upon entry of the present amendment, claims 1, 6, 15-17, 20, and 23 are canceled. New claims 31-33 are added. Claim 7 is amended to recite that the claimed reagent being (1) an antibody produced by the cells deposited at DSM as DSM ACC2548; (2) a humanized version of this antibody; or (3) a fragment of the antibody or the humanized antibody, provided that each of the humanized antibody and the fragment binds the same epitope of CD30 as the antibody produced by the cells deposited as DSM ACC2548. The amended claim 7 is merely a recast of the previously pending claim 7 and claim 1.

Claims 8-14, 18, 21, 22, and 24-30 are amended to improve clarity, to ensure proper antecedent basis, and to replace plural form with singular form.

Claim 19 is amended to recite the steps for diagnosing CD30-positive tumors or inflammatory diseases, support for which can be found, *e.g.*, in the first paragraph on page 10 of the specification. Claims 19 and 21 are also amended to recited a CD30-positive tumor, support for which can be found, *e.g.*, in original claim 23.

New claim 31 is added to recite that the claimed diagnostic method is carried out *in vitro*, which finds support in the specification, *e.g.*, in the first paragraph on page 10, where in line 4 it is stated, "[a] sample is taken from the patient," clearly indicating the performance of the diagnostic method *in vitro*. New claims 32 and 33 are added to present the subject matter of original claim 20, now canceled, in a claim format permissible under the U.S. patent law requirement.

Because no new matter is introduced by the present amendment, entry of this amendment is respectfully requested.

II. Claim Objections

In the Office Action of November 17, 2006, the Examiner objected to claims 1, 6, 7, 9, 11, and 15-18 for alleged improper antecedent basis, being drawn to a non-elected invention, and typographic errors. Applicants believe that these objections are obviated in view of the claim amendment present herein.

III. Sequence Requirements

The Examiner objected to the specification for failure to comply with the sequence requirements. Applicants have carefully reviewed the file history and note that a preliminary amendment was made on June 15, 2004, to insert sequence identifiers (SEQ ID NOs:1-12) to certain paragraphs on pages 12 and 15 of the specification. The only remaining sections of the specification that require further amendment to insert SEQ ID NO:13 following the sequence CEPDY have been identified by a word search and amended in this response. The objection over the sequence requirements is believed to have been overcome.

IV. Claim Rejections

A. 35 U.S.C. §112, Second Paragraph

Claims 1, 6, 7, 9, 11, 15-18, 29, and 30 were rejected under 35 U.S.C. §112, second paragraph, for alleged indefiniteness. Specifically, the Examiner argued that it was unclear whether "enters into interaction with ..." means "binds." This rejection is moot because the pending claims following the present amendment no longer recite the language of "enters into interaction with."

B. 35 U.S.C. §112, First Paragraph: Written Description

Claims 1, 6, 7, 9, 11, 15-18, 29, and 30 were also rejected under 35 U.S.C. §112, first paragraph, for alleged failure to comply with the written description requirement. Specifically, the Examiner asserted that the pending claims cover a broad genus of antibodies whose structure can potentially vary significantly from that of the antibody produced by deposited cells DSM AAC2548 and that the specification does provide adequate description for these antibodies.

To satisfy the written description requirement under 35 U.S.C. §112, first paragraph, a patent application must disclose the claimed invention in sufficient detail such that a person of ordinary skill in the art would reasonably conclude that the inventors had in their possession the claimed invention at the time the application was filed.

Although not agreeing with the Examiner's assertion, Applicants nonetheless have amended the pending claims to expedite prosecution. Following the amendment, claim 1 is canceled and claim 7 is now an independent claim, reciting a reagent that binds CD30 and is (1) an antibody produced by the DSM ACC2548 cells; (2) a humanized version of the antibody produced by the DSM ACC2548 cells; or (3) a fragment of the antibody produced by the DSM ACC2548 cells or the humanized antibody. Both the humanized antibody and the fragment bind CD30 at the same epitope as the antibody produced by the DSM ACC2548 cells. When the claimed reagent is defined in such specific language, Applicants contend that the antibodies (or fragments thereof) within the claim scope cannot possess a structure significantly varying from that of the antibody produced by the DSM ACC2548 cells. Indeed, as a person of skill in the art would recognize, humanization is a well known process of antibody manipulation in which the (usually) murine framework regions of the variable domains are replaced with the human framework regions. Any structural change in an antibody due to humanization is both specific and defined, *i.e.*, the skilled artisan can envision such a change.

Accordingly, Applicants strongly believe that, given the description found in the instant application and the state of the relevant art, a person of skill in the art would reasonably recognize that the present inventors had in their possession the claimed invention. It is therefore respectfully requested that the Examiner withdraw the written description rejection.

C. 35 U.S.C. §102

Claims 1, 6, 15-17, 29, and 30 were rejected under 35 U.S.C. §102(b) for alleged anticipation by Lemke *et al.* These claims were also rejected under 35 U.S.C. §102(e) for alleged anticipation by Molher *et al.* Applicants respectfully traverse the rejections, particularly in view of the present amendment.

On page 11 of the Office Action mailed November 17, 2006, the Examiner indicated that the antibody produced by the DSM ACC2548 cells (claim 7) and the isolated cell deposited as DSM ACC2548 (claim 18) are free of art. The amended claims are now drawn to a CD30-binding reagent, its composition, kit, and their uses. Since the structural features of the CD30-binding reagent in its CD30-binding domain are the same as the antibody produced by the DSM ACC2548 cells or contain only specifically defined modifications, Applicants submit that the subject matter of the amended claims is also free of art.

As such, the withdrawal of the anticipation rejections based on Lemke and Molher is respectfully requested.

D. 35 U.S.C. §103

Claims 9 and 11 were rejected under 35 U.S.C. §103(a) for alleged obviousness over Lemke *et al.* or Mohler *et al.* in view of Deonarain *et al.* Applicants respectfully traverse the rejection, particularly in view of the present amendment.

In order to establish a *prima facie* showing of obviousness, three requirements must be satisfied: all limitations of a pending claim must be expressly or impliedly disclosed by prior art references; there must be a suggestion or motivation in the art for one skilled artisan to combine the limitations; and there must be a reasonable expectation of success in making such a combination. MPEP §2143.

As discussed above, Lemke and Molher fail to provide at least one limitation of the pending claims: the specifically defined structural features in the CD30-binding domain of the claimed CD30-binding reagent. On the other hand, the Deonarain *et al.* reference was cited for the purpose of providing the limitations of an anti-CD30 antibody linked to an enzyme or a phosphodiesterase. The Deonarain reference therefore also fails to provide the missing limitation. It is hence clear that the cited references fail to provide all claim limitations. Accordingly, the obviousness rejection based on these references is improper and cannot be maintained.

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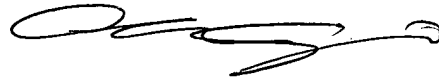
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CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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